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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,203	07/29/2003	Thomas Thisted	10062.210-US	1994

25908 7590 05/28/2009
NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER	
PROUTY, REBECCA E	
ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
05/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No.	Applicant(s)	
	10/630,203	THISTED ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41,43-49 and 51-58* is/are pending in the application.

4a) Of the above claim(s) *45 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,43,44,46-49,51-56 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-40, 42, and 50 have been canceled. Claims 41, 43-49, 51-57 and newly presented claim 58 are at issue and are present for examination.

Claims 45 and 57 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/5/08.

Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 is confusing in the recitation of "A variant of an alpha amylase comprising an amino acid sequence having at least 90% homology to SEQ ID NO:8..." as it is unclear whether it is the variant or the parent alpha amylase that must have the limitations recited following "comprising". It is suggested that the claim be amended to recite "A variant of an alpha amylase, said variant comprising an amino acid sequence having at least 90% homology to SEQ ID NO:8..." For purposes of further examination the suggested language is presumed to be what was intended.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41, and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersen et al. (US PG-PUBS 2003/0129718). The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. The rejection is explained in the previous Office Action.

Applicants argue that the examiner erred by referring to the AA560 amylase for support in this rejection. According to

Table 1 of both the instant specification and Table 1 of Andersen, AA560 and TERMAMYL brand amylase share 68.3 % identity. Thus, Anderson does not show the claimed combination of alterations including 90% homology. However applicants have misinterpreted the previous rejection and misstate the teaching of the Andersen reference. Andersen is NOT limited to making variants of the AA560 amylase but in fact teaches making variants of any Termamyl-like alpha amylase, including specifically the *Bacillus licheniformis* alpha amylase, i.e., the alpha amylase of SEQ ID NO:8 herein (see paragraph [0089]). The AA560 alpha amylase was referred to only because the position numbering of the positions to be varied are recited in Andersen with reference to the AA560 sequence instead of with reference of the *Bacillus licheniformis* alpha amylase sequence. The rejection is made because Andersen teaches making variants of the *Bacillus licheniformis* alpha amylase sequence at the positions in BLA corresponding to positions 172 and 185, 186, or 188 of the AA560 amylase. Since positions 172, 185, 186, and 188 of the AA560 amylase correspond to positions 170, 180, 181, and 183 of SEQ ID NO:8 herein, the teaching of making variants of the *Bacillus licheniformis* alpha amylase sequence at the positions in BLA corresponding to positions 172 and 185, 186, or 188 of the AA560 amylase is a teaching of a variant of SEQ ID

NO:8 herein with a modification at positions 170 and 180, 181, or 183.

Claims 41, 44, and 46-49 rejected under 35 U.S.C. 102(b) as being anticipated by Borchert et al. (WO 99/23211). The rejection is explained in the previous Office Action.

Applicants argue that the examiner erred by referring to the SP722 amylase for support in this rejection. According to Table 1 of the instant specification, SP722 and TERMAMYL brand amylase share 70.8 % identity. Thus, Borchert et al. does not show the claimed combination of alterations including 90% homology. However applicants have misinterpreted the previous rejection and misstate the teaching of the Borchert et al. reference. Borchert et al. is NOT limited to making variants of the SP722 amylase but in fact teaches making variants of any Termamyl-like alpha amylase, including specifically the *Bacillus licheniformis* alpha amylase, i.e., the alpha amylase of SEQ ID NO:8 herein (see paragraph [0089]). The SP722 alpha amylase was referred to only because the position numbering of the positions to be varied are recited in Borchert et al. with reference to the SP722 sequence instead of with reference of the *Bacillus licheniformis* alpha amylase sequence. The rejection is made because Borchert et al. teaches making variants of the *Bacillus licheniformis* alpha amylase sequence at the positions in BLA

corresponding to positions 172 and 184, 185, or 186 of the SP722 amylase. Since positions 172, 184, 185, and 186 of the SP722 amylase correspond to positions 170, 179, 180, and 181 of SEQ ID NO:8 herein, the teaching of making variants of the *Bacillus licheniformis* alpha amylase sequence at the positions in BLA corresponding to positions 172 and 184, 185, or 186 of the SP722 amylase is a teaching of a variant of SEQ ID NO:8 herein with a modification at positions 170 and 179, 180, or 181.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43 and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US PG-PUBS

2003/0129718). The rejection is explained in the previous Office Action.

Applicants argue that there is no evidence given by Andersen that an alpha-amylase that does not natively have a "Q" at position 170 could be modified to include a "Q" at this position to successfully create a variant in accordance with the present disclosure. However, this is not agreed with. As was previously stated in the rejection, the alignment of Termamyl-like α-amylases of Figure 1 of Andersen et al. shows that in some naturally occurring Termamyl-like α-amylases, the position which corresponds to position 170 of SEQ ID NO:8 herein is occupied with a glutamine residue. Since the three-dimensional structure of all Termamyl-like alpha amylases is highly similar, given that some Termamyl-like alpha amylases have a glutamine residue at this positions, a skilled artisan would reasonably expect that the three-dimensional structure of other Termamyl-like α-amylases would accommodate a glutamine at this position as well. Applicants argue that a reasonable expectation of success requires that the skilled person can predict that substitution of the residue at position corresponding to position 170 in SEQ ID NO:8 with a Q residue would result in an enzyme having alpha-amylase activity. However, applicants are reminded that obviousness does not require an absolute certainty of success

but merely a reasonable expectation thereof. The examiner has clearly explained why a skilled artisan would reasonably expect that the suggested substitution would produce a variant which retains alpha amylase activity.

Applicants also argue that the reference is devoid of any suggestion to make the specified alpha amylases except for using applicants disclosure. However this is not agreed with as it is Andersen et al. the specifically and explicitly suggest making variants having a substitution at the position corresponding to position 170 of SEQ ID NO:8. While Andersen do not specifically teach what amino acid this position should be substituted with it is obvious on its face that in order to make a substitution that a different amino acid need be selected and the natural amino acids only include 19 choices. The selection of any of these would be obvious but the rejection in fact provided a explanation of why a skilled artisan would select specifically glutamine. None of this rationale was taken from applicants disclosure.

Claims 41, 44 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borchert et al. (WO 99/23211) in view of Andersen et al. (US Patent 6,410,295). The rejection is explained in the previous Office Action.

Applicants argue that there is no evidence given by Borchert et al. or Andersen et al. that an amino acid sequence having at least 90% homology to SEQ ID NO.8, including an alteration at a position corresponding to position K170 in SEQ ID NO:8, and including an alteration at one or more of the specified positions (using SEQ ID NO:8 for numbering), would have alpha-amylase activity. However, this is not persuasive as both Borchert et al. and Andersen et al. teach multiple different variants including variants having modifications at the cited positions and teach that these variants all retain alpha amylase activity. The rejection merely suggests combining variant positions taught by each of the references together in one variant. As the art clearly teaches varying each of these positions while retaining activity and further teaches that these variants can be combined with others as well, a skilled artisan would reasonably expect that they could be combined and would retain activity. These is no reason advanced by applicants to suggest that the specific combination of variants recited would be inactive.

Applicants also argue that the references are devoid of any suggestion to make the specified alpha amylases except for using applicants disclosure. However this is not agreed with as both cited reference clearly teach the combination of the variants

described with other variant positions as well. As such each of the references clearly do suggest the claimed invention.

Claims 41, 43, 44, 46-49, 51-56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US PG-PUBS 2003/0129718) in view of Andersen et al. (US Patent 6,410,295). The rejection is explained in the previous Office Action.

Applicants argue that there is no evidence given by Andersen that an alpha-amylase that does not natively have a "Q" at position 170 could be modified to include a "Q" at this position to successfully create a variant in accordance with the present disclosure. However, this is not agreed with. As was previously stated in the rejection, the alignment of Termamyl-like α-amylases of Figure 1 of Andersen et al. shows that in some naturally occurring Termamyl-like α-amylases, the position which corresponds to position 170 of SEQ ID NO:8 herein is occupied with a glutamine residue. Since the three-dimensional structure of all Termamyl-like alpha amylases is highly similar, given that some Termamyl-like alpha amylases have a glutamine residue at this positions, a skilled artisan would reasonably expect that the three-dimensional structure of other Termamyl-like α-amylases would accommodate a glutamine at this position as well. Applicants argue that a reasonable expectation of success

requires that the skilled person can predict that substitution of the residue at position corresponding to position 170 in SEQ ID NO:8 with a Q residue would result in an enzyme having alpha-amylase activity. However, applicants are reminded that obviousness does not require an absolute certainty of success but merely a reasonable expectation thereof. The examiner has clearly explained why a skilled artisan would reasonably expect that the suggested substitution would produce a variant which retains alpha amylase activity.

Applicants also argue that the reference is devoid of any suggestion to make the specified alpha amylases except for using applicants disclosure. However this is not agreed with as it is Andersen et al. the specifically and explicitly suggest making variants having a substitution at the position corresponding to position 170 of SEQ ID NO:8. While Andersen do not specifically teach what amino acid this position should be substituted with it is obvious on its face that in order to make a substitution that a different amino acid need be selected and the natural amino acids only include 19 choices. The selection of any of these would be obvious but the rejection in fact provided a explanation of why a skilled artisan would select specifically glutamine. None of this rationale was taken from applicants disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652